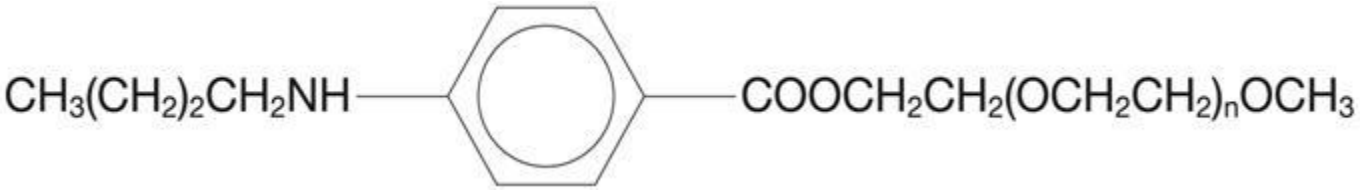
**BENZONATATE - benzonatate capsule**
Caraco Pharmaceutical Laboratories, Ltd.

**DESCRIPTION**
Benzonatate, a non-narcotic oral antitussive agent, is 2, 5, 8, 11, 14, 17, 20, 23, 26-nonaoxaoctacosan- 28-yl p-(butylamino) benzoate. The molecular formula is $C_{30}H_{53}NO_{11}$ with a molecular weight of 603.7.




Each capsule, for oral administration, contains 100 mg or 200 mg of benzonatate, USP.
Inactive ingredients are: Alcohol, ammonium hydroxide, D&C Yellow 10, gelatin, glycerin, propylene glycol, purified water, shellac glaze, simethicone and titanium dioxide. In addition, the capsule may contain trace amounts of fractionated coconut oil.

**CLINICAL PHARMACOLOGY**
Benzonatate acts peripherally by anesthetizing the stretch receptors located in the respiratory passages, lungs, and pleura by dampening their activity and thereby reducing the cough reflex at its source. It begins to act within 15 to 20 minutes and its effect lasts for 3 to 8 hours. Benzonatate capsules have no inhibitory effect on the respiratory center in recommended dosage.

**INDICATIONS AND USAGE**
Benzonatate capsules are indicated for the symptomatic relief of cough.

**CONTRAINDICATIONS**
Hypersensitivity to benzonatate or related compounds.

**WARNINGS**
Severe hypersensitivity reactions (including bronchospasm, laryngospasm and cardiovascular collapse) have been reported which are possibly related to local anesthesia from sucking or chewing the capsule instead of swallowing it. Severe reactions have required intervention with vasopressor agents and supportive measures.
Isolated instances of bizarre behavior, including mental confusion and visual hallucinations, have also been reported in patients taking benzonatate capsules in combination with other prescribed drugs.

**PRECAUTIONS**
Benzonatate is chemically related to anesthetic agents of the para-amino-benzoic acid class (e.g. procaine; tetracaine) and has been associated with adverse CNS effects possibly related to a prior sensitivity to related agents or interaction with concomitant medication.

**Information for Patients:**
Release of benzonatate from the capsule in the mouth can produce a temporary local anesthesia of the oral mucosa and choking could occur. Therefore, the capsules should be swallowed without chewing.

**Pregnancy:**
*Pregnancy Category C.* Animal reproduction studies have not been conducted with benzonatate. It is also not known whether benzonatate can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Benzonatate capsules should be given to a pregnant woman only if clearly needed.

**Nursing Mothers:**
It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk caution should be exercised when benzonatate capsules are administered to a nursing woman.

**Carcinogenesis, Mutagenesis, Impairment of Fertility:**
Carcinogenicity, mutagenicity, and reproduction studies have not been conducted with benzonatate.

**Pediatric Use:**
Safety and effectiveness in children below the age of 10 have not been established.

**ADVERSE REACTIONS**
Potential adverse reactions to benzonatate capsules may include:
Hypersensitivity reactions including bronchospasm, laryngospasm, cardiovascular collapse possibly related to local anesthesia from chewing or sucking the capsule.

**CNS:** sedation; headache; dizziness; mental confusion; visual hallucinations.
**GI:** constipation; nausea; GI upset.
**Dermatologic:** pruritus; skin eruptions.
**Other:** nasal congestion; sensation of burning in the eyes; vague “chilly” sensation; numbness of the chest; hypersensitivity.
Rare instances of deliberate or accidental overdose have resulted in death.

**OVERDOSAGE**
Overdosage may result in death.
The drug is chemically related to tetracaine and other topical anesthetics and shares various aspects of their pharmacology and toxicology. Drugs of this type are generally well absorbed after ingestion.

**Signs and Symptoms:**
If capsules are chewed or dissolved in the mouth, oropharyngeal anesthesia will develop rapidly. CNS stimulation may cause restlessness and tremors which may proceed to clonic convulsions followed by profound CNS depression.

**Treatment:**
Evacuate gastric contents and administer copius amounts of activated charcoal slurry. Even in the conscious patient, cough and gag reflexes may be so depressed as to necessitate special attention to protection against aspiration of gastric contents and orally administered materials. Convulsions should be treated with a short-acting barbiturate given intravenously and carefully titrated for the smallest effective dosage. Intensive support of respiration and cardiovascular-renal function is an essential feature of the treatment of severe intoxication from overdosage.
Do not use CNS stimulants.

**DOSAGE AND ADMINISTRATION**
Adults and Children over 10: Usual dose is one 100 mg or 200 mg capsule t.i.d. as required. If necessary, up to 600 mg daily may be given.

**HOW SUPPLIED**
Benzonatate capsules, USP 100 mg are clear, yellow liquid filled in oval-shaped softgel capsule, imprinted “133” in white ink. The capsules are available as:
NDC 57664-133-88 Bottles of 100
NDC 57664-133-13 Bottles of 500
Benzonatate capsules, USP 200 mg are clear, yellow liquid filled in oval-shaped softgel capsule, imprinted “134” in white ink. The capsules are available as:
NDC 57664-134-88 Bottles of 100
NDC 57664-134-13 Bottles of 500
**Store at 20° - 25°C (68° - 77°F).** (See USP Controlled Room Temperature).
**PROTECT FROM LIGHT.**
**Dispense** in a tight, light-resistant container as defined in the USP, with a child-resistant closure (as required). **KEEP TIGHTLY CLOSED**.
**Distributed by:**
Caraco Pharmaceutical Laboratories, Ltd.
Detroit, MI 48202
Affiliate of
**Sun Pharmaceutical Industries, Inc.**
Stock # 6351T01
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**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL- 100 MG 100 COUNT**
**NDC 57664-133-88**
**Benzonanate Capsules, USP**
**100 mg**
**Rx only**
**100 Capsules**


**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL- 100 MG 500 COUNT**
**NDC 57664-133-13**
**Benzonanate Capsules, USP**
**100 mg**
**Rx only**
**500 Capsules**


**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL- 200 MG 100 COUNT**
**NDC 57664-134-88**
**Benzonanate Capsules, USP**
**200 mg**
**Rx only**
**100 Capsules**


**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL- 200 MG 500 COUNT**
**NDC 57664-134-13**
**Benzonanate Capsules, USP**
**200 mg**
**Rx only**
**500 Capsules**